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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/733,306 | 12/08/2000 | Margaret A. Schwarz | 9022.20 | 3192 |

20792 7590 04/26/2004

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| EXAMINER |
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EPPS FORD, JANET L

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| ART UNIT | PAPER NUMBER |
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1635

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-04-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413)

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 112

2. Claims 1-2, 4, 6-11, 14, and 16-19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for practicing the claimed method by the administration of monoclonal antibodies targeting EMAP II, does not reasonably provide enablement for practicing the claimed method comprising the administration of antisense oligonucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, for the reasons of record set forth in the Official Action mailed 11-03-03.

3. Applicant's arguments filed 2-04-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection of the grounds that since Applicants have cancelled claims directed to administration of antisense oligonucleotides, the instant claims are enabled. Additionally, Applicants noted that the cancellation of dependent claims 5 and 15 was not intended to alter the meaning of the independent claims. Contrary to Applicant's assertions, it is noted that although Applicants have amended the claims specifically directed to antisense oligonucleotide administration, by Applicant's own admission, it is noted that the meaning of the independent claims has not been altered by Applicant's amendment, therefore the administration of antisense oligonucleotide is still encompassed within pending claims 1-2, 4, 6-11, 14, and 16-19. Therefore, since there are no other arguments addressing the merits of the scope rejection of

these claims for lack of enablement as set forth in the prior Office Action, the instant claims remain rejected for the reasons of record.

4. Claims 1-4, 6-14, and 16-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the prior Office Action mailed 11-03-03.

5. Applicant's arguments filed 2-04-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by way of amending the instant claims to "include recitations directed to the treatment of human subjects, in which human EMAP II would, of course, reside." Moreover, Applicants argue that Human EMAP II is known. Based upon this amendment Applicants respectfully requested that the rejection of claims 1-19 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement, be withdrawn.

6. Contrary to Applicant's assertions, the instant claims are not adequately described by the specification as filed. First it is noted that the claims are not limited to the use of agents that specifically binds to or inhibits the expression of human EMAP II, the claims still read on agents with specifically binds to or inhibits the expression of any EMAP II (protein or nucleic acid). As stated in the prior Office Action, the instant claims do not recite any particular nucleotide sequence and/or amino acid sequence to describe the structure of EMAP II. Since there is no structure recited in the instant claims to describe the EMAP II of the claimed invention, the instant claims read on EMAP II isolated from any organism, including all polymorphic and

allelic variants, as well as any splice variants that my encode EMAP II. However, the specification as filed provides only a brief reference to human EMAP II according to GenBank Accession No. 10119. It is noted that the instant claims are not limited to human EMAP II, or furthermore human EMAP II according to GenBank Accession No. 10119. Moreover, Applicant's generic reference to EMAP II in the claims does not provide sufficient description such that the skilled artisan could envision the structures of all forms of EMAP II encompassed by the instant claims, or the full scope of antisense and/or antibodies that would be useful to practice the claimed invention as well.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

Since Applicants have not provided a clear and precise description of the full scope of compounds encompassed by the instant claims. Applicants were not in possession of the full scope of the claimed methods recited in the instant claims.

Double Patenting

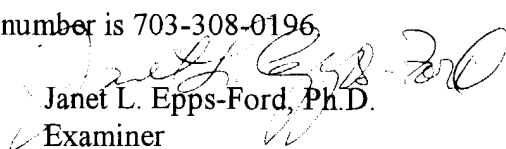
7. Claims 1-19 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/928,796, for the reasons of record set forth in the prior Office Action mailed 11-03-03.

8. In the response filed 2-04-04, Applicants stated that upon allowance a Terminal Disclaimer would be filed if determined to be necessary. Since this rejection is provisional, Applicants are allowed to hold their response in abeyance until the indication of allowable subject matter.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635